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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,254	08/14/2008	Doug Bettenhausen	61198-371 (47381)	6435
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McCarter & English, LLP 265 Franklin St. BOSTON, MA 02110			EXAMINER ROYDS, LESLIE A	
			ART UNIT 1629	PAPER NUMBER
			MAIL DATE 04/21/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,254

Applicant(s)

BETTENHAUSEN ET AL.

Examiner

Leslie A. Royds Draper

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-26 are presented for examination.

Requirement for Election/Restriction

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required to make the following election(s) consistent with the below instructions:

(A) Election of a single disclosed species of disease for which the subject is receiving radiotherapy from those specifically recited in, i.e., instant claims 8 or 20, i.e., (1) gastrointestinal malignancies, (2) urogenital malignancies, (3) gynecologic malignancies, or (4) osteogenic and other sarcomatous malignancies in which the pelvic structures are involved.

(A)(i) Should Applicant elect (1) gastrointestinal malignancies as the species of disease for which the subject is receiving radiotherapy for examination, then Applicant is required to further elect a single disclosed species of gastrointestinal malignancy from those specifically recited, which are: (a) **colorectal cancer**; (b) **appendiceal cancer**; (c) **anal cancer**; or (d) **small bowel cancer**.

(A)(ii) Should Applicant elect (2) urogenital malignancies as the species of disease for which the subject is receiving radiotherapy for examination, then Applicant is required to further elect a single disclosed species of urogenital malignancy from those specifically recited, which are: (e) **prostate cancer**; (f) **bladder cancer**; (g) **testicular cancer**; or (h) **penile cancer**.

(A)(iii) Should Applicant elect (3) gynecologic malignancies as the species of disease for which the subject is receiving radiotherapy for examination, then Applicant is required to further elect a single disclosed species of gynecologic malignancy from those

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specifically recited, which are: **(i) cervical cancer; (j) endometrial cancer; (k) ovarian cancer; (l) vaginal cancer; or (m) vulvar cancer.**

Applicant is cautioned that the election of a particular specie of disease, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

The following claims are generic: 1-26.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species of diseases do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are unrelated to one another because the disorders recited in the present claims for which the compound(s) must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.), response to therapy, and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, vaginal cancer, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treat a distinct disorder, such as penile cancer. Furthermore, each is considered to be unrelated to the others because the patient populations, dosage amounts, therapeutic response and therapeutic protocol for treating the claimed disorders are each unique to the type of disorder being treated.

Applicant is required, in reply to this action, to elect a single species in accordance with the instructions supra to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention or species.

Should Applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), Applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a request under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Note that the Examiner may consider additional requirements for restriction and/or election of species that will result in an additional office action(s) as a result of any amendments made to the instant claims that clarify and/or alter the scope of subject matter instantly claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds Draper whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on (571)-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1629

April 19, 2011